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10/804,762	03/19/2004	Yan Qi	108674-010201	8100
35893	7590	05/11/2009	EXAMINER	
GREENBERG TRAURIG, LLP			KELLY, ROBERT M	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/804,762	<b>Applicant(s)</b> QI ET AL.
	<b>Examiner</b> ROBERT M. KELLY	<b>Art Unit</b> 1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 13 March 2009.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1,5,6,14,15,17 and 40-53 is/are pending in the application.
- 4a) Of the above claim(s) 40-53 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1,5,6,14,15 and 17 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/06)  
 Paper No(s)/Mail Date 3/13/09
- 4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date \_\_\_\_\_
- 5) Notice of Informal Patent Application
- 6) Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(c) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/14/08 has been entered.

The amendment of 2/27/09 is entered.

Claims 1, 5, and 6 are amended.

Claims 18-26 are cancelled.

Claims 1, 5, 6, 14, 15, 17, and 40-53 are presently pending.

### ***Election/Restrictions***

It is noted that Applicant has cancelled Claims 18-26, drawn to non-elected inventions.

Newly submitted claims 40-53 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

As noted in the restriction requirement of 11/21/05, and the election of 12/27/05, Applicant elected the methods of inhibiting an immune response to allogenic transplants (Group I) over the choice of electing the allografts themselves (Group II). Hence, Claims 40-53, being within the scope of Group II, are necessarily non-elected.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution

on the merits. Accordingly, claims 40-53 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 1, 5, 6, 14, 15, and 17 are presently considered.

***IDS of 3/13/09***

Applicant's IDS has been considered. It is officially noted that the Chinese documents were signed off on the basis of the translation paragraphs provided by Applicant, which reflects what they consider to be relevant, and the Examiner does not recognize the document as a whole as being considered, but only the translations paragraphs provided.

***Claim Rejections - 35 USC § 112 - clarity***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 14, 15, and 17 are newly rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 contains a preamble for a method for producing a cell designed to inhibit development of an adaptive T cell response, but at no point in the method is there a conclusion evidencing that such cell is made. Hence, the Artisan would not be aware of the metes and bounds, e.g., if further steps are required.

Claims 14, 15, and 17 are rejected for depending from a rejected base claim and not overcoming the lack of clarity in such base claim.

***Claim Rejections - 35 USC § 112 - enablement***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

In light of the amendments, the rejections of Claims 1, 14, 15, and 17 under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling, are withdrawn.

To wit, Applicant no longer claims inhibiting development of a T cell response, but now claims making the cell which so-inhibits.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejections of Claims 1, 5, 6, 14, 15 and 17 under 35 U.S.C. 102(b) as being anticipated by any one of U.S. Patent Nos. 5,623,056, 5,601,828 or 5,242,687, each to Tykocinski, et al., are withdrawn.

To wit, Tykocinski does not discuss the use of gutless vectors for transforming the cells/tissue.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 5, 6, 14, 15, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over any one of U.S. Patent Nos. 5,623,056, 5,601,828 or 5,242,687, each to Tykocinski, et al., and U.S. Patent No. 6,156,497 to Kaleko.

Each patent is described in terms of the 5,601,828 patent, as they have similar disclosures as per the rejected subject matter.

With regard to Claims 1, 5, and 6, Tokocinski teaches specific and non-specific immunomodulation, enhancement of cellular engraftment, and modulation of non-immune cells achieved by using various membrane-binding and soluble CD8 compositions (e.g., ABSTRACT). Such CD8 is specifically defined in the specification to be CD8 alpha (col. 5, paragraph 3). Further such CD8 may be made in membrane bound form, using either the natural CD8 transmembrane sequence, or using other transmembrane sequences attached to the CD8 alpha functional domain (e.g., col. 7, paragraph 4). Further, such cells may be transformed to express the CD8 molecule on its surface (e.g., col. 11, paragraph 2). Such cells and compositions are taught to suppress T cell activation through the proximity of the CD8 molecule with the alloantigen (e.g., col. 3, paragraph 4). Still further, to enhance allogenic engraftment, the cells are coated with CD8 prior to transplantation, which the Artisan would recognize to

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include either the transgenic expression, or the other methods of such coating described in the specification.

With regard to Claims 15 and 17, the human CD8 alpha chains are disclosed (e.g., col. 5, paragraph 4).

Moreover, it is noted that some of the claims in the 5,623,056 patent are drawn to the cells expressing CD8 and the antigen (e.g., Claims 15-19).

However, the Tykocinski reference does not discuss the use of gutless vectors to deliver the genes to the cells.

On the other hand, Kaleko teaches gutless adenoviral vectors to transform tissue, which offers an advantage over non-gutless vectors, in that the amount of transgene which can be incorporated is high, and further that the toxicity and immunogenicity of the adenoviral backbone genes can be avoided.

Hence, the Artisan would have found it obvious to modify Tykocinski to use the gutless vectors of Kaleko to deliver the transgene to the cell(s). The Artisan would be motivated to do so to minimize possible immune responses, as such are the point of the method to begin with. Moreover, the Artisan would have a reasonable expectation of success, as Tykocinski teaches that the methods work, and Kaleko teaches that the adenoviral vectors have the advantage of increased transgene size options as well as reduced possible toxic and immune response.

*Response to Argument – Tykocinski references*

Applicant's response of 11/14/08 has been fully considered but is not found persuasive.

Applicant argues that the Tykocinski patents fail to teach non-immunogenic vectors (pp. 7-8).

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Such is not persuasive. The present rejection is based on obviousness and utilizes gutless vectors which Applicant's own specification is cited for teaching as non-immunogenic vectors (e.g., paragraph 0134 of the Application Publication).

### ***Conclusions***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT M. KELLY whose telephone number is (571)272-0729. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert M Kelly/  
Primary Examiner, Art Unit 1633